



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/076,632	02/19/2002	Paul Habermann	DEAV2001-0008 US NP	2603
5487	7590	08/12/2009		
ANDREA Q. RYAN SANOFI-AVENTIS U.S. LLC 1041 ROUTE 202-206 MAIL CODE: D303A BRIDGEWATER, NJ 08807			EXAMINER STEADMAN, DAVID J	
			ART UNIT 1656	PAPER NUMBER
			NOTIFICATION DATE 08/12/2009	DELIVERY MODE ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

USPatent.E-Filing@sanofi-aventis.com  
andrea.ryan@sanofi-aventis.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/076,632	<b>Applicant(s)</b> HABERMANN, PAUL	
	<b>Examiner</b> David J. Steadman	<b>Art Unit</b> 1656	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 26 May 2009.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,7-14,21-28 and 30-35 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,7-14,21,25-28 and 33-35 is/are rejected.
- 7) ☒ Claim(s) 22-24 and 30-32 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Status of the Application***

- [1]** Claims 1, 7-14, 21-28, and 30-35 are pending in the application.
- [2]** Applicant's amendments to the claims, filed on 5/26/09, are acknowledged. This listing of the claims replaces all prior versions and listings of the claims.
- [3]** Applicant's arguments filed on 5/26/09 in response to the non-final Office action mailed on 12/12/08 have been fully considered and are deemed to be persuasive to overcome at least one of the rejections and/or objections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.
- [4]** The text of those sections of Title 35 U.S. Code not included in the instant action can be found in a prior Office action.

### ***Claim Objections***

- [5]** Claim 1 is objected to in the recitation of "...sequence coding for hirudin..." and in order to improve claim form, it is suggested that the noted phrase be amended to recite, *e.g.*, "...sequence encoding hirudin..."
- [6]** Claim 1 uses the designation "AsmR" (using lowercase "s") in line 2 and "ASm" (using uppercase "S") in line 11. In order to improve claim form, it is suggested that, *e.g.*, "ASm" be replaced with "Asm" in line 11, which maintains consistency with "AsmR" in claims 31-33.

Art Unit: 1656

**[7]** Claim 1 is objected to in the recitation of “n=O” and “m=O” (using the letter “O”) and in order to improve claim form, it is suggested that the noted phrases be amended to recite, *e.g.*, “n=0” and “m=0” (using zero).

**[8]** Claims 14, 25, and 27 are objected to in the recitation of “production of fusion protein” in lines 1 of the claims. Although it is reasonably clear that “fusion protein” refers to a fusion protein of hirudin and mini-proinsulin, in order to improve claim form, it is suggested that the noted phrase be amended to recite, *e.g.*, “production of a hirudin-mini-proinsulin fusion protein”.

**[9]** Claims 30-35 are objected to in the recitation of “A process” or “A nucleic acid” and in order to maintain consistent use of claim terminology and improve claim form, it is suggested that “A” in the noted phrases be replaced with “The”.

**[10]** Claim 33 is objected to in the recitation of “(Gly-Asn-Ser-Ala-Arg)” and in order to improve claim form, it is suggested that the noted term be amended to recite, *e.g.*, “(Gly-Asn-Ser-Ala-Arg)”.

***Claim Rejections - 35 USC § 112, Second Paragraph***

**[11]** The rejection of claims 1, 7-14, 21-28, and 30-35 under 35 U.S.C. 112, second paragraph, is withdrawn in view of the instant claim amendment to delete the limitations that were the bases of the rejections, namely “a hirudin derivative which is at least about 80% homologous thereto”, “a derivative thereof which is at least about 90% homologous thereto”, and “T is the 3' segment of the sequence coding for bovine interleukin 2 which remains after cleavage thereof with NcoI restriction enzyme”.

**[12]** Claims 33-35 are newly rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

By the instant claim amendment, claim 1 limits "Hir" to a nucleic acid encoding hirudin. However, claims 33 (claim 34 dependent therefrom) and 35 define "Hir" as encoding lepirudin and thus lack clarity with respect to the scope of polypeptides that are encompassed by "Hir". It is noted that claim 33, by reciting "Hir encodes hirudin or lepirudin" indicates there is a distinction between hirudin and lepirudin. It is suggested that applicant clarify the meaning of the claims.

***Claim Rejections - 35 USC § 112, First Paragraph***

**[13]** The written description and scope of enablement rejections of claims 1, 7-14, 21-28, and 30-35 under 35 U.S.C. 112, first paragraph, are withdrawn in view of the instant claim amendment to delete the limitations that were the bases of the rejections, namely "a hirudin derivative which is at least about 80% homologous thereto", "a derivative thereof which is at least about 90% homologous thereto", and "T is the 3' segment of the sequence coding for bovine interleukin 2 which remains after cleavage thereof with NcoI restriction enzyme".

***Claim Rejections – Double Patenting***

Art Unit: 1656

**[14]** The provisional rejection of claims 1 and 7-13 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 6-12, and 38 of co-pending application 10/076,631 is maintained for the reasons of record and the reasons set forth below. The provisional rejection was fully explained in a prior Office action. See item 19 at p. 12 of the Office action mailed on 12/12/08.

RESPONSE TO ARGUMENT: At p. 6 of the instant remarks, applicant responds by stating, "Applicants propose to take appropriate action to remove this rejection if it still exists at the time when the Office indicated that allowable claims are present in the application". Applicant's argument is not found persuasive to overcome the provisional rejection. It should be noted that according to USPTO records, the claims of the '631 application are allowed.

**[15]** The rejection of claims 1, 9, 12-14, 21, and 25-28 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 2-5, 8, and 10-18 of US Patent 7,202,059 in view of Dörschug et al. and Schmid et al. is maintained for the reasons of record and the reasons set forth below. The rejection was fully explained in a prior Office action. See item 20 beginning at p. 12 of the Office action mailed on 12/12/08.

RESPONSE TO ARGUMENT: At p. 6 of the instant remarks, applicant responds by stating, "Applicants propose to take appropriate action to remove this rejection if it still exists at the time when the Office indicated that allowable claims...are present in the application". Applicant's argument is not found persuasive to overcome the

Art Unit: 1656

rejection. Applicant is advised that appropriate action to remove this rejection must occur *prior to* an indication that the claims are in condition for allowance.

### **Conclusion**

**[16]** Status of the claims:

- Claims 1, 7-14, 21-28, and 30-35 are pending.
- Claims 1, 7-14, 21, 25-28, and 33-35 are rejected.
- Claims 30-32 are objected to for reasons noted above.
- Claims 22-24 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.
- No claim is in condition for allowance.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J. Steadman whose telephone number is 571-272-0942. The examiner can normally be reached on Mon to Fri, 7:30 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1656

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/David J. Steadman/  
Primary Examiner, Art Unit 1656